DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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May 26, 2015

J.C.E.C. Company, Inc.
c/o Ms. Elizabeth N. Dupras, RAC
B&H Consulting Services, Inc.
50 Division Street, Suite 206
Somerville, NJ 08876

Re: K142549
Trade/Device Name: Oral7™ Moisturizing Gel
Oral7™ Moisturizing Mouthwash
Oral7™ Moisturizing Mouth Spray
Regulation Number: Unclassified
Regulation Name: Saliva, Artificial
Product Code: LFD
Dated: April 24, 2015
Received: April 27, 2015

Dear Ms. Dupras:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142549

Device Name
Oral7™ Moisturizing Gel, Oral7™ Moisturizing Mouthwash and Oral7™ Moisturizing Mouth Spray

Indications for Use *(Describe)*
Relieve symptoms of dry mouth, refresh, moisturize, clean and soothe oral irritation, and lubricate oral dryness.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) SUMMARY (K142549)

5.1. Submitter Information

- **Sponsor**

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President

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- **Regulatory Agent**

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- **Date of Summary**

21 May 2015

5.2. Device Name

The proposed Oral7™ devices are outlined in Table 5-1.

Table 5-1: Proposed Oral7™ Device Names

Proprietary Name	Common/Usual Name	Classification Name (Product Code)
Oral7™ Moisturizing Gel	Saliva, Artificial	Saliva, Artificial (LFD)
Oral7™ Moisturizing Mouthwash	Saliva, Artificial	Saliva, Artificial (LFD)
Oral7™ Moisturizing Mouth Spray	Saliva, Artificial	Saliva, Artificial (LFD)

Regulatory Class: Unclassified
Product Code: LFD

5.3. Equivalent Device Identification

The primary predicate device for Oral7™ Moisturizing Gel is Oral Balance Gel (K061331); the primary predicate device for Oral7™ Moisturizing Mouthwash and Oral7™ Moisturizing Mouth Spray is Biotène® Dry Mouth Oral Rinse (K101477).

The formulation of Oral7™ Moisturizing Mouthwash is identical to the formulation of Oral7™ Moisturizing Mouth Spray. The products have the same intended use, technical characteristics and physiological purpose; the only difference is in the mode of delivery. Therefore, Biotène® Moisturizing Mouth Spray (K103745) is a reference predicate for Oral7™ Moisturizing Mouth Spray.

The predicate devices are outlined in Table 5-2.

Table 5-2: Predicate Devices

Product	Notification Holder	510(k) Number
Primary Predicates		
Oral Balance Gel	Laclede, Inc.	K061331
Biotène® Dry Mouth Oral Rinse	GlaxoSmithKline Consumer Healthcare	K101477
Reference Predicate		
Biotène® Moisturizing Mouth Spray	GlaxoSmithKline Consumer Healthcare	K103745

5.4. Device Descriptions

Oral7™ products are specially formulated saliva substitutes which contain moisturizers, humectants, proteins and salivary enzymes that collectively have lubricating, moisturizing, soothing and refreshing properties to relieve and treat the symptoms of dry mouth. The Oral7™ products are listed in Table 5-3.

Table 5-3: Oral7™ Product Presentations

Product	Presentation
Oral7™ Moisturizing Gel	1.6 fluid ounces (48 mL) in plastic aluminum barrier laminate tube with membrane
Oral7™ Moisturizing Mouthwash	8.5 and 16.9 fluid ounces (250 and 500 mL, respectively) in white, polyethylene terephalate bottles
Oral7™ Moisturizing Mouth Spray	1.5 fluid ounces (44 mL) in white, polyethylene terephalate bottles

5.5. Intended Use

The intended use of the devices is symptomatic treatment of xerostomia.

Indications for Use: Relieve symptoms of dry mouth, refresh, moisturize, clean and soothe oral irritation, and lubricate oral dryness.

5.6. Comparison Table

A comparison of the Oral7™ products and the primary and reference predicate devices is provided in Table 5-4.

Table 5-4: Comparison of Oral7™ Products to the Primary and Reference Predicate Devices

Parameter	*Primary Predicate Devices*				*Reference Predicate Device*	
	Gel		**Mouthwash and Mouth Spray/ Oral Rinse**		**Mouth Spray**	
	Oral7™	**Oral Balance (K061331)**	**Oral7™**	**Biotène® (K101477)**	**Oral7™**	**Biotène® (K103745)**
Intended Use	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia	Symptomatic treatment of xerostomia
Method of Use	Ready to use gel	Ready to use gel	Ready to use liquid	Ready to use liquid	Ready to use spray	Ready to use spray
Applications/Day	As needed	As needed	As needed	As needed	As needed	As needed
Disease State	Xerostomia	Xerostomia	Xerostomia	Xerostomia	Xerostomia	Xerostomia
Area of Use	Oral cavity	Oral cavity	Oral cavity	Oral cavity	Oral cavity	Oral cavity
Type of Product	Gel	Gel	Liquid	Liquid	Liquid	Liquid
Presentation	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile

5.7. Summary of Testing

5.7.1. Nonclinical Testing

Biocompatibility testing for the final finished devices was conducted according to ISO 10993-1. Testing for cytotoxicity (ISO 10993-5), sensitization and irritation (ISO 10993—10) were completed. The cytotoxicity testing showed mild reactivity, which was not unexpected due to the known sensitivity/nature of the test (i.e., use of bare cells) and the presence of lysozyme, lactoperoxidase, mentha piperita and potassium thiocyanate in the formulations. The mild reactivity of the formulations supports the use in the proposed indication and does not impact safe use of the formulations. The sensitization and oral mucosal irritation testing demonstrated that the formulations are non-sensitizing and non-irritating.

5.7.2. Clinical Testing

The submission does not contain clinical testing.

5.7.3. Bench Testing

Stability testing has been conducted on three (3) batches each of Oral7™ Moisturizing Gel and Oral7™ Moisturizing Mouthwash. Oral7™ Moisturizing Mouth Spray has the identical formulation as Oral7™ Moisturizing Mouthwash. Both formulations are filled into polyethylene terephalate bottles; therefore, stability data for the Oral7™ Moisturizing Mouthwash support the shelf-life of Oral7™ Moisturizing Mouth Spray.

The data demonstrate that there are no significant changes in any of the product characteristics over the three year period of study for Oral7™ products. Available data support a three (3) year shelf-life for the Oral7™ products.

5.8. Conclusion

The subject Oral7™ products have the same materials (i.e., moisturizers, humectants, proteins and salivary enzymes) as the primary predicate devices. All ingredients in the Oral7™ products are commonly used for their intended functions at equivalent or higher levels than in the proposed formulation.

In addition, the Oral7™ products have the same intended use and the same technological properties as the primary and reference predicate devices. The Oral7™ products were shown to be safe for the intended use in tests for cytotoxicity, sensitization and irritation.

The materials and manufacturing/processing of the Oral7™ products are the same as the primary predicate devices; therefore, there is no impact on safety and effectiveness of the subject devices.

Given the similarities in chemical composition, available delivery forms and physical properties between the Oral7™ products and the Biotène primary and reference predicate devices, Oral7™ Moisturizing Gel, Oral7™ Moisturizing Mouthwash and Oral7™ Moisturizing Mouth Spray are as safe and as effective as the primary and reference predicate devices.